

PATENT Customer No. 22,852 Attorney Docket No. 7579.0015-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re A	application of:)	
Graha	m Edmund KELLY et al.)	Group Art Unit: 1614
Serial	No.: 10/600,004)	Examiner: Cybille DELACROIX-MUIRHEID
Filed:	June 18, 2003)	Confirmation No.: 6037
For:	COMPOSITIONS FOR CARDIOVASCULAR AND BONE TREATMENT USING FORMONONETIN AND OTHER ISOFLAVONES (as amended)))))	
Comm P.O. B	STOP AMENDMENT dissioner for Patents dox 1450 adria, VA 22313-1450		
Sir:			

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicants bring to the attention of the Examiner the documents listed on the attached Form PTO 1449. This Third Supplemental Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by Section 1.17(p).

These documents are U.S. patents and U.S. applications that are possibly related to the pending application by subject matter. This Third Supplemental Information Disclosure Statement supplements the Information Disclosure Statements filed in the U.S. Patent and Trademark Office on September 11, 2003, and January 6, 2004.

U.S. Patent or Application Number	Attorney Docket Number	Title	Examiner
10/799,022 (2004-0170713)	07579.0005-06000	Method Of Cholesterol Reduction Using Isoflavones	Not Yet Assigned
Not Yet Assigned	07579.0012-02000	Composition and Method for Protecting Skin from UV Induced Immunosuppression and Skin Damage	Not Yet Assigned
10/851,270	07579.0014-01000	Production of Isoflavone Derivatives	Not Yet Assigned
10/493,390	07579.0021-00000	6-Hydroxy isoflavones, derivatives and medicaments invloving same	Not Yet Assigned

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form. Should the Examiner conclude that any of these claims form the basis of a rejection, the Examiner is invited to contact the undersigned.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicant determines that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any further fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: December 13, 2004

Deborah J. Acker

Reg. No. 48,916

Atty. Docket No.	07579.0015-01000	Appln. No.	10/600,004	
Applicant Graham Edmund KELLY et al.				
Filing Date	June 18, 2003	Group:	1614	

	U.S. PATENT DOCUMENTS						
	Examiner Initial*	Document Number	Issue Date/ Publication Date	Name	Class	Sub Class	Filing Date If Appropriate
0	1 E 16	2004-0170713 A1	Sep. 2, 2004	Kelly	424	757	
DEC	1 3 2004						

PRADEMARKS	FOREIGN PATENT DOCUMENTS					
	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)						
U.S. Patent Application entitled "Composition and Method for Protecting Skin from UV Induced Immunosuppression and Skin Damage," filed on September 21, 2004, as a Continuation Application of U Patent Application No. 10/212,847, filed August 5, 2002. (specification as filed - WO 99/36050; and peciliars after Preliminary Amendment of September 21, 2004)							
	U.S. Patent Application No. 10/851,270 entitled "Production of Isoflavone Derivatives," filed on May 20, 2004. (specification as filed - WO 00/49009)						
	U.S. Patent Application No. 10/493,390 entitled "6-Hydroxy Isoflavones, Derivatives and Medicaments Involving Same," filed on April 24, 2004. (specification as filed - WO 03/035635)						
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Examiner	Date Considered		
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw lin citation if not in conformance and not considered. Include copy of this form with next communication applicant.			
Form PTO 1449	Pater	nt and Trademark Office - U.S. Department of Commerce	



PATENT Customer No. 22,852 Attorney Docket No. 07579.0015-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Graham Edmund KELLY et al.) Group Art Unit: 1614
Application No.: 10/600,004) Examiner: Cybille DELACROIX-) MUIRHEID
Filed: June 18, 2003)
For: COMPOSITIONS FOR CARDIOVASCULAR AND BONE) Confirmation No. 6037
TREATMENT USING	
FORMONONETIN AND OTHER ISOFLAVONES (as amended)) }

MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicants bring to the attention of the Examiner the documents listed on the attached Form PTO 1449. This Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Second Supplemental Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by Section 1.17(p).

In view of the potential relatedness of this case to the others set forth in the Information Disclosure Statements, submitted on September 11, 2003, and January 6, 2004, Applicants

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submit the references cited in these cases. This submission should not be construed, however, as an admission of relatedness.

Applicants wish to direct the Office's attention to Interference Proceeding No. 104,576 involving the Gorbach U.S. Patent No. 5,498,631 ("the '631"). In that interference, Stanley Gorbach was the senior party. The junior party, Graham Edmund Kelly, one of the inventors in this application, successfully argued the priority of U.S. Application Serial No. 08/910,837. Thus, to the extent that the presently pending claims are similar to the Kelly claims in interference, the '631 Gorbach patent is not a proper reference under Section 102.

To assist the Office in its review of these documents, Applicants offer the following information. Specifically, in foreign applications related to applications Serial Nos. 09/602,191, 10/274,371, 10/611,087, 10/611,151, 10/799,022 and U.S. Patents Nos. 6,497,906, 6,562,380, and 6,642,212 (Attorney Docket Nos. 07579-0001-00, and 07579-0005-00; 07579-0005-01; 07579-0005-02; 07579-0005-03; 07579-0005-04; 07579-0005-05; 07579-0005-06), third parties initiated opposition proceedings in Australia and New Zealand. Applicants submit the following declarations from those proceedings:

- 1. Statutory Declaration of Joseph Nicolas Van Haaster.
- 2. Statutory Declaration of Norbert Krause.
- 3. Statutory Declaration of Hubert Regtop.
- 4. Statutory Declaration of Kerry Martin Bone.
- 5. Statutory Declaration of Nancy Beckham.
- 6. Statutory Declaration of G. Clements.
- 7. Statutory Declaration of Fiona Bathgate.
- 8. Statutory Declaration of Julie Hill.

- 9. Statutory Declaration of Ngaire Petit-Young.
- 10. Statutory Declaration of Jennifer Carpinelli.

This Second Supplemental Information Disclosure Statement also submits documents cited in the other applications set forth in the chart submitted in the Information Disclosure Statements filed on September 11, 2003, and January 6, 2004. Copies of the listed documents are attached unless already provided in the U.S. Patent Application No. 09/914,035, filed December 10, 2001, now abandoned, upon which Applicants rely for the benefits provided in 35 U.S.C. § 120. German published application DE 44 32 947 A1 and Grunert et al. are not in English. In lieu of a statement of relevance or translation of the non-English documents, English language versions of the EPO Supplementary Partial Search Report dated October 11, 2002, from U.S. Patent No. 6,599,536 (Attorney Docket No. 07579-0013-00) and the EPO Communication dated March 8, 2002, from U.S. Patent No. 6,562,380 (Attorney Docket No. 07579-0005-00) citing these documents are enclosed. Schultz, in German, and Deschamps-Vallet, in French, have certified English translations attached. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Application No. 10/600,004 Attorney Docket No. 7579.0015-01000

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any additional fee due in connection with the filing of this Statement, please charge the fee to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: December 13, 2004

Deborah J. Acker



Atty. Docket N	O. 07579-0015-01000	Serial No. 10/600,004	
Applicant	KELLY et al.	Confirmation No. 6037	
Filing Date	June 18, 2003	Group: 1614	

U.S. PATENT DOCUMENTS						
Examiner Initial*	Document Number	Issue/Publication Date	Name	Class	Sub Class	Filing Date If Appropriate
	2002 0035074-A1	Mar. 25, 2002	KELLY			
	2002-0198248 A1	Dec. 26, 2002	KELLY et al.			
	2003-0018060 A1	Jan. 23, 2003	KELLY et al.			
	2003-0059384 A1	Mar. 27, 2003	KELLY et al.			
	2003-0078214 A1	Apr. 24, 2003	KELLY			
,	2003-0157225 A1	Aug. 21, 2003	HUSBAND et al.			
	2003-0219499 A1	Nov. 27, 2003	KELLY et al.	·		
	2004-0048812 A1	Mar. 11, 2004	KELLY			
	2004-0072765 A1	Apr. 15, 2004	KELLY et al.			
	2004-0106561 A1	Jun. 3, 2004	KELLY			
	2004-0116498 A1	Jun. 17, 2004	HUSBAND			
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	3,535,344	10/20/1970	Irmscher et al.			
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	4,157,984	06/12/1979	Zilliken			
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·	4,264,509	04/28/1981	Zilliken			
	4,301,251	11/17/1981	Rumyantseva et al.			
	4,366,082	12/28/1982	Zilliken			

Examiner Date Considered		Date Considered	
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; d through citation if not in conformance and not considered. Include copy of this form with recommunication to applicant.			
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Atty. Docket No.	07579-0015-01000	Serial No. 10/600,004
Applicant	KELLY et al.	Confirmation No. 6037
Filing Date	June 18, 2003	Group: 1614

	U.S. PATENT DOCUMENTS					
Examiner Initial*	Document Number	Issue/Publication Date	Name	Class	Sub Class	Filing Date If Appropriate
	4,390,559	06/28/1983	Zilliken			
	4,428,876	01/31/1984	lwamura			
	4,814,346	03/21/1989	Albert et al.			
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	5,506,211	04/09/1996	Barnes et al.			
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	5,530,112	06/25/1996	Greenshields et al.			
	5,547,866	08/20/1996	Durzan et al.			
	5,554,519	09/10/1996	Weber et al.			
	5,569,459	10/29/1996	Shlyankevich			
	5,637,561	06/10/1997	Shen et al.			
	5,639,785	06/17/1997	Kung			
	5,679,806	10/21/1997	Zheng et al.			
	5,700,669	12/23/1997	Hanson et al.			
	5,702,752	12/30/1997	Gugger et al.			

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		U.S. PATE	NT DOCUMENTS			
Examiner Initial*	Document Number	Issue/Publication Date	Name	Class	Sub Class	Filing Date If Appropriate
	5,726,034	03/10/1998	Bryan et al.			
	5,733,926	03/31/1998	Gorbach			
	5,763,389	06/09/1998	Shen et al.	·		
	5,789,581	08/04/1998	Matsuura et al.			
	5,792,503	08/11/1998	Gugger et al.			
	5,804,234	09/08/1998	Suh et al.			
	5,830,887	11/03/1998	Kelly			
	5,855,892	01/05/1999	Potter et al.			
	5,942,539	08/24/99	Hughes, Jr. et al.			
	6,004,558	12/21/1999	Thurn et al.			
	6,146,668	11/14/2000	Kelly et al.			
	6,340,703 B1	01/22/2002	Kelly			
	6,455,032 B1	09/24/2002	Kelly et al.			
	6,497,906 B1	12/24/2002	Kelly			
	6,562,380 B1	05/13/2003	Kelly			
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	6,642,212 B1	11/04/2003	Kelly			
	6,649,648 B1	11/18/2003	Kelly et al.			

	FOREIGN	PATENT DOCUMEN	TS		
Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No

Examiner		Date Considered				
*Examiner:	niner: Initial if reference considered, whether or not citation is in conformance with MPEP 6 through citation if not in conformance and not considered. Include copy of this form communication to applicant.					
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Atty. Docket No.	07579-0015-01000	Serial No. 10/600,004
Applicant	KELLY et al.	Confirmation No. 6037
Filing Date	June 18, 2003	Group: 1614

-	•	FOREIGN	N PATENT DOCUM	ENTS		
-	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	AU-B-80655/87	05/05/1988	Australia			
· · · · · ·	AU-A-10227/95	7/27/1995	Australia			
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	JP S50-0035393	04/04/1975	Japan			Abstract
	JP S50-101360 A	08/11/1975	Japan			Abstract
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	JP S62-106016 A	05/16/1987	Japan			Abstract
	JP S62-106017 A	05/16/1987	Japan			Abstract

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	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	JP S62-126186 A	06/08/1987	Japan			Abstract
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	JP H01-226824 A	09/11/1989	Japan			Abstract
	JP H01-258669 A	10/16/1989	Japan			Abstract
	JP H02-067218 A	03/07/1990	Japan			Abstract
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_	JP H02-124883 A	05/14/1990	Japan	·		Abstract
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	JP H05-170756 A	07/09/1993	Japan			Abstract
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	JP H10-059956 A	03/03/1998	Japan			Abstract
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	WO 93/23069	11/25/1993	PCT			
	WO 94/23716	10/27/1994	PCT .			
	WO 95/03293 A1	02/02/1995	PCT			
	WO 96/10341 A1	04/11/1996	PCT			

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Atty. Docket No.	07579-0015-01000	Serial No. 10/600,004
Applicant	KELLY et al.	Confirmation No. 6037
Filing Date	June 18, 2003	Group: 1614

		FOREIGN	N PATENT DOCU	IMENTS	· 	- · · · · ·
	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
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Examiner	Date Considered
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Form PTO 14	Patent and Trademark Office - U.S. Department of Commerce

Atty. Docket No.	07579-0015-01000	Serial No. 10/600,004
Applicant	KELLY et al.	Confirmation No. 6037
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	FOREIGI	N PATENT DOCL	MENTS		
Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
WO 03/035635 A1	05/01/2003	PCT		-	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
Adlercreutz, H. et al., "Determination of Urinary Lignans and Phytoestrogen Metabolites, Potential Antiestrogens and Anticarcinogens, in Urine of Women on Various Habitual Diets," <i>J. steroid Biochem.</i> , Vol. 25, No. 58, pp. 791-797 (1986).
Adlercreutz, H. et al., "Dietary Phytoestrogens and Cancer: In Vitro and In Vivo Studies," J. Steroid Biochem. Molec. Biol., Vol. 41, No. 3-8, pp. 331-337 (1992).
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Akkad, Andrea A., et al., "Abnormal Uterine Bleeding on Hormone Replacement: The Importance of Intrauterine Structural Abnormalities," <i>Obstetrics & Gynecology</i> , Vol. 86, pp. 330-334 (1995).
Alegrio, L.V. et al.; "Diarylheptanoids and Isoflavonoids from <i>Centrolobium</i> Species," <i>Phytochemistry</i> , Vol. 28, No. 9, pp. 2359-2362, (1989).
Al-Maharik, N.I. et al., "Synthesis of C-C-Bridged Bis-Isoflavones," J. Org. Chem., Vol. 65, pp. 2305-2308, (2000).

Examiner		Date Considered	
*Examiner:		sidered, whether or not citation is in conformance with MPEP 609; draw line in conformance and not considered. Include copy of this form with next blicant.	
Form PTO 14	149	Patent and Trademark Office - U.S. Department of Commerce	

Atty. Docket No.	07579-0015-01000	Serial No. 10/600,004
Applicant	KELLY et al.	Confirmation No. 6037
Filing Date	June 18, 2003	Group: 1614

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
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